SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE RE: DOCUMENT NUMBER K_052082

Beckman Coulter Ferritin on the Access® Immunoassay Systems

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable:

1. *Beckman Coulter Ferritin on the Access® Immunoassay Systems (K926221).*
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed.**

   The changes were *1) Addition of an auto-dilution feature that allows a 1:10 on-board system dilution of serum and plasma samples using the Access Wash Buffer. The auto-dilution feature is for all Access Immunoassay Analyzers (Access, Access 2, SYNCHRON LXi 725 and UniCel Dxl 800) and this modification requires addition of a second assay protocol file to all Access Immunoassay Analyzer. The reportable range using the auto-dilution feature is 1300 ng/mL to ~ 15,000 ng/mL (10 times the highest calibrator value). A mix step is included in the dilution vessel for Access, Access 2 and LXi. 2) Modification of the assay protocol file to ensure the main pipettor drops to a certain depth in the reagent pack to improve particle mixing and sufficient aspiration of reagents for transfer to the reaction vessel. 3) Addition of a description of the auto-dilution feature in the package insert.*
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including *labeling, intended use, indication for use, methodology, sample matrix, kit component specification and analytical performance*.
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis - *Failure mode and effects analysis (see Section G, p.38)*
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied *(see Section G, p. 38)*
   c) A declaration of conformity with design controls *(see Section H, p. 40)*. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
6. A **Truthful and Accurrate Statement,** a **510(k) Summary** and the **Indications for Use Enclosure.**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared device.